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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

Max D. Hensley
Gilead Sciences, Inc.
353 Lakeside Drive
Foster City, CA 94404

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,142,051

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,142,051, which claims the human drug product VISTIDE™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 305 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 305 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 18, 1996 (61 Fed. Reg. 66675). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,266 - 130) + 267
= 1,403 days

Since the regulatory review period began April 17, 1992, before the patent issued (August 25, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From April 17, 1992 to August 25, 1992 is 130 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 26, 1996) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 1,403 days, would extend the patent to June 28, 2013, which is beyond the 14 year limit (14 years after the approval date is June 26, 2010) set forth in 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its expiration date, August 25, 2009, to and including June 26, 2010, or 305 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,142,051
Granted	:	August 25, 1992
Original Expiration Date	:	August 25, 2009
Applicant	:	Antonin Holy et al.
Owner of Record	:	Institue of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic and Rega Institut
Title	:	N-Phosphonylmethoxyalkyl Derivatives of Pyrimidine and Purine Bases and a Therapeutical Composition Therefrom with Antiviral Activity
Classification	:	544/243
Product Trade Name	:	VISTIDE™ (cidofovir)
Term Extended	:	305 days
Expiration Date of Extension	:	June 26, 2010

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: VISTIDE™
FDA Docket No.: 96E-0380